Cortisone
(–) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diethylpropion
Diflunisal
Digoxin
Diphenhydramine
Domperidone
Doxylamine
Ecgonine
Ecgonine methyl-ester
(+) Ephedrine
(±) Ephedrine
(–) Ephedrine
(–) Ψ Ephedrine
Erythromycin
ß-Estradiol
Estrone-3-sulfate
Ethyl-p-amino-benzoate
Fenoprofen
Furoxmide
Gentisic acid
Glutethimide
Guaifenesin
Hippuric acid
Hydralazine
Hydrochloro-thiazide
Hydrocortisone
O-Hydroxy-hippuric acid
3-Hydroxy-tyramine
Ibuprofen
Imipramine
Iproniazid
(–) Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Lidocaine
Loperamide
Loxapine succinate
Maprotiline
Meprobamate
Methadone
p-Hydroxymeth-amphetamine
Methaqualone
Methoxyphen-amine
(±) 3,4-Methylene-dioxyamphet-amine
(±) 3,4-Methylene-dioxymeth-amphetamine
Methylphenidate
Methyprylon
Nalidixic acid
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norethindrone
Noroxymorphone
D-Norprop-oxyphene
(–) Norpseudo-ephedrine
Noscapine
Nylidrin
D,L-Octopamine
Oxalic acid
Oxazepam
Oxolinic acid
Oxymetazoline
Papaverine
Penicillin-G
Pentazocaine
Pentobarbital
Perphenazine
Phendimetrazine
Phenelzine
Phenobarbital
Phentermine
Phentoin
L-Phenylephrine
ß-Phenylethyl-amine
Phenylpropanol-amine
Prednisolone
Prednisone
Promazine
Promethazine
D,L-Propanolol
Propiomazine
D-Propoxyphene
D-Pseudo-ephedrine
Quinidine
Quinine
Rantidine
Salicylic acid
Secobarbital
Serotonin
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Δ^8-THC
Δ^9-THC
11-nor-Δ^9-THC-9-COOH
Tetrahydro-cortisone
Tetrahydrozoline
Thiamine
Thioridazine
D,L-Thyroxine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D,L-Tryptophan
Tyramine
D,L-Tyrosine
Uric acid
Verapamil
Zomepirac

References

1. Hawks RL, Chiang CN, eds. *Urine Testing for Drugs of Abuse.* Rockville, MD: National Institute on Drug Abuse (NIDA), Research Monograph 73;1986.
2. Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man.* 2nd Ed., Davis, CA: Biomedical Publ.;1982;p. 488.

Symbols Key

	Manufactured by
CE	CE Mark
EC REP	Authorized Representative
IVD	*In Vitro* Diagnostic Medical Device
REF	Catalog Number
	Consult Instructions for Use
LOT	Batch Code
EXP YYYY-MM-DD	"Use By" date in year-month-day format
2°C (35°F) Min / 30°C (86°F) Max	Temperature Limitation
Σ n	Contains sufficient for <n> tests
	Do not reuse
CONT	Contents
DEV	Test Device
PIP	Transfer Pipette
IFU	Instructions for Use
TEST DRUG	One-step immunochromatographic Assay for the Detection of Drugs of Abuse in Urine
TEST PCP	Phencyclidine Test

Patent No.: 5,559,041

CE

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AccuSign® PCP

One-Step Phencyclidine Test

For *In Vitro* Use Only

Simple One-Step Immunoassay for the Qualitative Detection of Phencyclidine in Urine

PBM

Catalog No. DOA-205-35 35 Test Kit
DOA-205-10 10 Test Kit

Intended Use

AccuSign® PCP is a simple, one-step immunochromatographic assay for the rapid, qualitative detection of phencyclidine at a cutoff concentration of 25 ng/mL in human urine.

The* AccuSign® PCP *test provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography, mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmatory methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.[1]

Summary and Explanation

Phencyclidine is an arylcyclohexylamine that is used as a veterinary anesthetic. It is used illegally as a hallucinogen, and is commonly referred to as PCP, angel dust, love boat, hog, or killer weed. PCP can produce lethargy, euphoria, ataxia, nystagmus and coma. Phencyclidine is readily absorbed when smoked or ingested, or even through skin contact. It is metabolized in the liver. About 10% of the dose is excreted in urine as the parent compound, phencyclidine.[2]

Principle

The **AccuSign® PCP** test uses solid-phase immunoassay technology for the qualitative detection of phencyclidine in human urine. The test is based on the principle of the highly specific immunochemical reactions between antigens and antibodies which are used for the analysis of specific substances in biological fluids. The test relies on the competition for binding to the antibodies between drug conjugates and drugs which may be present in the urine sample. In the test procedure, a sample of urine is placed in the Sample well of the device and is allowed to migrate upward. If drug is present in the urine sample, it competes with the drug conjugate, which is immobilized on the membrane, for the limited antibodies present in the form of dye-antibody conjugate. When a sufficient amount of drug or drug metabolite above the cutoff level is present, the drug will saturate the antibodies, thus inhibiting the binding of dye-antibody conjugate to the drug conjugate on the membrane. This prevents the formation of a line on the membrane. Therefore, a drug-positive urine sample will not generate a line at the Test position in the Result Window, indicating a positive result from positive drug competition, while a negative urine sample will generate a line at the Test position in the Result Window, indicating a negative result from an absence of competition with free drug.

In addition to the Test line that may appear in the Result Window, a Control line is present at the Control position (C) to confirm the viability of the test. This Control line (validation line) should always appear if the test is conducted properly. The Control line is immobilized with monoclonal anti-mouse antibody; therefore, it will capture the monoclonal antibody-dye conjugates that pass the region, producing a colored line at the Control position (validation line). This works as a procedural control, confirming that proper sample volume was used and the reagent system worked. If insufficient sample volume is used, there may not be a Control line, indicating the test is invalid.

Materials Provided

The **AccuSign® PCP** test kit contains all the reagents necessary to perform the tests.

- **AccuSign® PCP** device. The test device contains a membrane strip coated with PCP drug conjugate and a pad containing monoclonal anti-phencyclidine antibody-dye conjugate in a protein matrix.
- Disposable specimen dispensers.
- Instructions for use.

Precautions

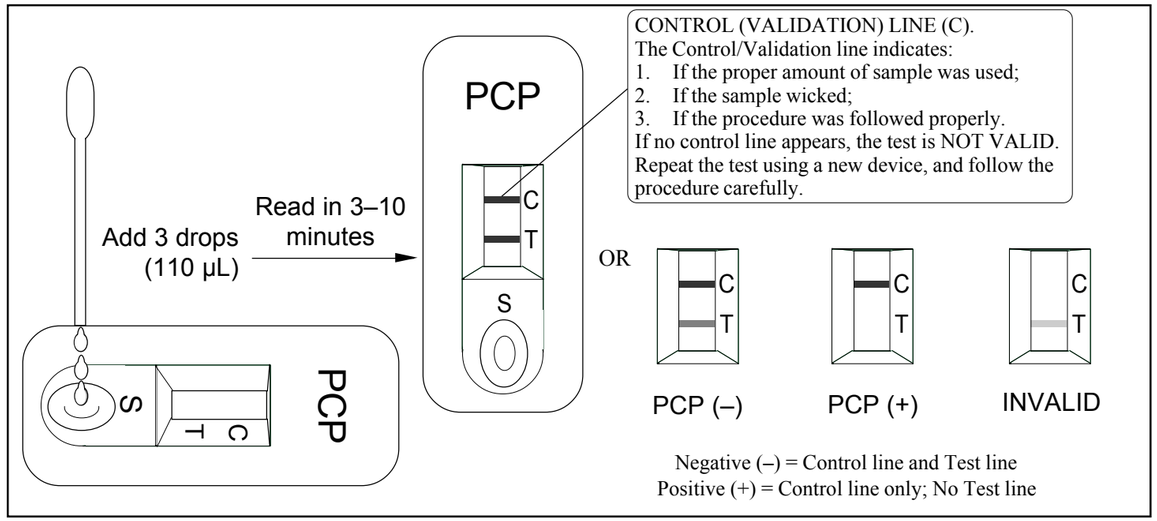
- For *in vitro* diagnostic use only.
- Avoid cross contamination of urine samples by using a new urine specimen container and dropper for each urine sample.
- The test kit does not contain any HIV or hepatitis infective components.
- Urine specimens are potentially infectious. Proper handling and disposal methods should be followed according to good laboratory practices.
- The **AccuSign®** device should remain in its original sealed pouch until ready for use. Do not use the test if the pouch is damaged or the seal is broken.
- Do not use the test kit after the expiration date.

Storage and Stability

The **AccuSign® PCP** test kit should be stored at 2–30°C (35–86°F) in the original sealed pouch. The expiration dating was established under these storage conditions.

Specimen Collection and Preparation

Approximately 110 µL of urine sample is required for each test. Fresh urine specimens do not require any special handling or pretreatment. Specimens should be collected in a clean glass or



plastic container. If testing will not be performed immediately, specimens should be refrigerated (2–8°C) or frozen. Frozen specimens must be completely thawed and thoroughly mixed before using.

Specimens containing a large amount of particulate matter may give inconsistent test results. Such specimens should be clarified by centrifuging or allowing to settle before testing.

Test Procedure

The test procedure consists of adding the urine sample to the Sample well of the device and watching for the appearance of colored lines in the result window.

Test Protocol

1. For each test, open one **AccuSign® PCP** pouch and label the **AccuSign®** with the patient ID.
2. Holding the dropper vertically, dispense 3 drops (110 µL) of the urine sample into the Sample well (**S**).
3. Read the result after 3 minutes, but within 10 minutes of sample application.

Interpretation of Results

Negative: The appearance of a reddish-purple Control line (**C**) and a line next to T indicates a negative test result; i.e., no drug above the cutoff level has been detected. The color intensities of the Control line and the Test line may not be equal. *Any faint line at the T position in the Result window, visible in 10 minutes, should be interpreted as negative. A negative test result does not indicate the absence of drug in the sample; it only indicates the sample does not contain drug above the cutoff level in qualitative terms.*

Positive: The appearance of only a reddish-purple Control line and no distinct line next to T indicates the test result is positive for PCP (i.e., the specimen contains PCP at a concentration above the cutoff level). *A positive test result does not provide any indication of the level of intoxication or urinary concentration of the drug in the sample; it only indicates the sample contains drug above the cutoff level in qualitative terms.*

Invalid: A distinct Control line (**C**) should always appear. The test is invalid if no Control line forms at the **C** position. Such tests should be repeated with a new **AccuSign® PCP** test device.

Limitations

- The test is designed for use with unadulterated urine only.
- There is a possibility that factors such as technical or procedural errors, as well as other substances in the urine sample which are not listed in Table 4 below, may interfere with the test and cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results. If adulteration is suspected, the test should be repeated with a new sample.
- This test detects only the presence of phencyclidine in human urine. A positive test result does not provide any indication of the level of intoxication or urinary concentration.
- The test result read after 10 minutes may not be consistent with the original reading obtained within the 10 minute reading period. The test must be read within 10 minutes of sample application.

User Quality Control

Internal Control: Each **AccuSign®** test device has built-in controls. The Control line is an internal positive procedural control. A distinct reddish-purple Control line should always appear at the C position, if the test procedure is performed properly, an adequate sample volume is used, the sample and reagent are wicking on the membrane, and the test reagents at the control line and the conjugate-color indicator are reactive. In addition, if the test has been performed correctly and the device is working properly, the background in the result window will become clear and provide a distinct result. This may be considered an internal negative procedural control.

The positive and negative procedural controls contained in each **AccuSign®** test device satisfy the requirements of testing a positive control and a negative control on a daily basis. If the Control line does not appear at the Control position, the test is invalid and a new test should be performed. If the problem persists, contact PBM for technical assistance.

External Control: External controls may also be used to assure that the reagents are working properly and that the assay procedure is followed correctly. It is recommended that a control be tested at regular intervals as good laboratory testing process. For information on how to obtain controls, contact PBM's Technical Services.

Expected Values

AccuSign® PCP is a qualitative assay. The amount of phencyclidine present in the urine cannot be estimated by the assay. The assay results distinguish positive from negative samples. Positive results indicate the samples contain phencyclidine above the cutoff concentration.

Performance Characteristics

The **AccuSign® PCP** test has been shown to detect phencyclidine at an average cutoff of 25 ng/mL in urine.

The accuracy of **AccuSign® PCP** was evaluated in comparison to a commercially available immunoassay (Abuscreen ONLINE™ PCP Assay) at a cutoff of 25 ng/mL. A total of 157 samples was tested by both procedures. Complete agreement was observed in 98.7% of the samples as shown below (Table 1).

Table 1. Accuracy: Comparison of AccuSign® PCP with Abuscreen ONLINE™ PCP

		Abuscreen ONLINE™ PCP		
		Positive	Negative	TOTAL
AccuSign® PCP	Positive	53	0	53
	Negative	2	102	104
TOTAL		55	102	157
		Relative Sensitivity	Relative Specificity	
PCP		96.4% (53/55)	> 99% (102/102)	

Analysis of discrepant samples for PCP showed they were within 25% of the cutoff value.

In a separate study, **AccuSign® PCP** was evaluated against specimens confirmed as positive by GC/MS. The results below demonstrate the excellent correlation of **AccuSign® PCP** with GC/MS (> 99% agreement, Table 2).

Table 2. Accuracy: Comparison of AccuSign® PCP with GC/MS Assay

		AccuSign®	GC/MS
PCP	Positive	21	21
	Negative	0	0

Precision and Accuracy

The precision of the **AccuSign® PCP** assay was determined by carrying out the test with serially diluted standard drug solutions. About 95% of the samples containing phencyclidine concentrations 25% over the cutoff level consistently showed positive results.

The study also included over 40 samples ± 25% cutoff level. These results were found to be consistently in agreement with expected test results.

Distribution of Random Error:

Twenty (20) blind samples prepared by spiking various concentrations of phencyclidine were separately tested by two operators. The test results from the two operators showed complete agreement.

Reproducibility

The reproducibility of the test results of the **AccuSign® PCP** assay was examined at three different sites using a total of 15 blind controls, consisting of 5 negative samples, 5 moderately positive samples (50-70 ng/mL phencyclidine), and 5 strongly positive samples (100-200 ng/mL phencyclidine). The results obtained at these three sites with these controls demonstrated 100% agreement with each other.

Specificity

Compounds that are detected by the **AccuSign® PCP** test are listed below. The specificity of the **AccuSign® PCP** test was determined by adding the drugs and drug metabolites listed to drug-negative urine specimens and testing with the **AccuSign® PCP** test kit. The results are expressed in terms of the concentration required to produce a positive result (Table 3).

Table 3. Specificity

Compound	Concentration (ng/mL)
Phencyclidine	25
Thienylcyclohexyl-piperidine	450

The following compounds show no cross-reactivity when tested with **AccuSign® PCP** at a concentration of 100 µg/mL (Table 4).

Table 4. Non Cross-Reacting Compounds

4-Acetamidophenol	D,L-Amphetamine	Cannabinol
Acetophenetidin (Phenacetin)	L-Amphetamine	Chloralhydrate
	Apomorphine	Chloramphenicol
N-Acetylprocainamide	Aspartame	Chlordiazepoxide
	Atropine	Chlorothiazide
Acetylsalicylic acid	Benzilic acid	Chlorpromazine
Aminopyrine	Benzoic acid	Chlorquine
Amitryptyline	Benzoylecgonine	Cholesterol
Amobarbital	Benzphetamine	Clomipramine
Amoxapine	Butabarbital	Clonidine
Amoxicillin	Cannabidiol	Cocaine